

DOCKET NO.: CELG00401  
Application No.: 10/762,897  
Office Action Dated: September 8, 2004

PATENT

This listing of claims will replace all prior versions, and listings, of claims in the application.

**Listing of Claims:**

1-12. (Canceled)

13. (New) A method for distributing a teratogenic drug to a patient in need of the drug while preventing foetal exposure to the drug, said method comprising:

- a. registering in a computer readable storage medium physicians permitted to prescribe said drug;
- b. providing said patient with information concerning the teratogenic risks attendant to foetal exposure to said drug;
- c. obtaining the informed consent of said patient to receive said drug despite said risks;
- d. registering said patient in said medium, including information concerning the ability of said patient to become pregnant or to impregnate a female;
- e. upon a determination that said patient is capable of becoming pregnant or capable of impregnating a female, determining that said patient is not currently pregnant or counseling said patient capable of impregnating a female to use a contraceptive device or formulation when engaging in sexual intercourse with a female, and registering same in said medium;
- f. permitting said patient access to said drug only after consulting said medium to verify that said patient (1) is a female who is not pregnant or (2) is a female incapable of becoming pregnant or (3) is a male who has been counseled to use a contraceptive device or formulation when engaging in sexual intercourse with a female.

14. (New) The method of claim 13 wherein said teratogenic drug is thalidomide.

15. (New) The method of claim 13 wherein said contraceptive device is a condom.

16. (New) The method of claim 13 wherein said access to said drug is provided in the form of a prescription.

17. (New) The method of claim 16 wherein said prescription is for no more than about 28 days.

18. (New) The method of claim 16, wherein before said prescription is refilled, said method further comprises:

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g. obtaining additional information regarding the likelihood that said patient may have become pregnant, and, based upon said additional information determining whether said patient could have become pregnant during the previous 28 days; and

h. upon a determination that said patient could have become pregnant, administering a pregnancy test to verify that said patient is not currently pregnant, before said prescription is filled.

19. (New) The method of claim 16, further comprising providing said patient capable of becoming pregnant with contraceptive counseling.

20. (New) The method of any preceding claim, further comprising providing said patient with a contraceptive device or formulation.

21. (New) The method according to claim 13, further comprising registering said patient and said pharmacy in a computer readable storage medium.